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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/964,273      | 09/26/2001  | Sean Brynjelsen      | IFT-5776            | 9945             |

7590 06/19/2007  
ASSISTANT GENERAL COUNSEL  
BAXTER INTERNATIONAL INC.  
LAW DEPARTMENT  
ONE BAXTER PARKWAY, DF2-2E  
DEERFIELD, IL 60015

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| EXAMINER |
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KISHORE, GOLLAMUDI S

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| ART UNIT | PAPER NUMBER |
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1615

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| MAIL DATE | DELIVERY MODE |
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06/19/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |   |  |  |
|------------------------------|---|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/964,273          | <b>Applicant(s)</b><br>BRYNJELSEN ET AL. |  |
|                              | <b>Examiner</b><br>Gollamudi S. Kishore, Ph.D | <b>Art Unit</b><br>1615                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 21-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The amendment dated 9-1-06 is acknowledged.

Claims included in the prosecution are 1-19 and 21-38.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7, 11 and 21-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al (5,916,596) as set forth in the previous action.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the claims 1 and 25 have been amended to clarify that the sonication takes place at a temperature below the room temperature and causes the evaporation of essentially all of the water immiscible organic solvent to cause the pharmaceutically active agents to precipitate from the organic solvent into the aqueous solution. Applicant further argues that the office suggests that it is well known in the art to use sonication as an organic solvent removal method, but fails to point to art that demonstrates that sonication was known as method of solvent removal. These arguments are not persuasive. First of all, the art of Popescu (6,090,406), which is already on record, clearly shows the removal of organic solvent by sonication (Example 1). Secondly, there are organic solvents such as ether and alcohol with low boiling points, which evaporate by themselves without any external manipulation in course of

time. Since sonication process involves external force, it is within the skill of the art to realize that the solvent evaporation is faster than when the solvents are left alone by themselves. Instant claims do not recite any time limitation. The amendment to the claims reciting that the temperature is below the room temperature will not overcome this rejection since the room temperature varies from lab to lab and country to country and does not reflect the actual temperature. Even assuming that the claims recite a specific temperature, the examiner points out that such steps are manipulatable parameters practiced by an artisan especially when the active agent is heat sensitive. The examiner cites the reference of Caza (6,079,508) to show that there are some ultrasonic processors, which remove the solvent (see col. 6, lines 9-17). The examiner also cites Werling (2003/0096013) which shows sonication removes solvent (0059). Third, instant claim language 'comprising' does not exclude other evaporation conditions carried out simultaneously. The examiner cites the references of Janoff and Popescu (5,009,819), which teach concurrent evaporation by Nitrogen while sonicating the emulsion of interest (col. 31, lines 25-30 of Janoff; Example 1 of Popescu).

3. Claims 1-7, 11, 21-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al. US 5916596 in view of Popescu US 6090406 as set forth in the previous action.

Applicant's arguments have been fully considered, but are not persuasive. The examiner has already addressed applicant's arguments regarding Desai. Applicant argues that in Popescu, the temperature is 12 degrees above the boiling point of ether. The examiner has already addressed these arguments.

3. Claims 1-19 and 21-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Violanto (4,826,689) in combination with Parikh (5,922,355) as set forth in the previous action.

4. Claims 1-19 and 21-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Violanto (4,826,689) in combination with Parikh (5,922,355), further in view of Popescu (6,090,406) as set forth in the previous action

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again pertain to the solvent removal by sonication. These have already been addressed by the examiner.

The above rejections are maintained.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

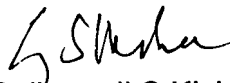
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is

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(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK